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John Lemanowicz
SmithKline Beecham Corp.
Corporate Intellectual Property Department
Five Moore Drive
Research Triangle Park, N.C. 27709

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,713,485

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,713,485, which claims the human drug product TYKERB® (lapatinib) and methods of using TYKERB® (lapatinib), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 630 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 630 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of November 10, 2008 (73 Fed. Reg. 66647). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,078 - 1,181) + 182
	=	630 days (1.7 years)

Since the regulatory review period began January 5, 2001, before the patent issued (March 30, 2004), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 5, 2001, to and including March 30, 2004, is 1,181 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 6,713,485

Granted:	March 30, 2004
Original Expiration Date[1]:	January 8, 2019
Applicant:	Malcolm C. Carter et al.
Owner of Record:	SmithKline Beecham Corp.
Title:	Heterocyclic Compounds
Product Trade Name:	TYKERB® (lapatinib)
Term Extended:	630 days
Expiration Date of Extension:	September 29, 2020

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: TYKERB® (lapatinib)
Docket No.: FDA-2007-E-0229